(12) UK Patent Application (19) GB (11) 2 255 918 (13) A

(43) Date of A publication 25.11.1992

(21) Application No 9208178.5

(22) Date of filing 13.04.1992

(30) Priority data
(31) 9109064 (32) 26.04.1991 (33) GB

(51) INT CL[5]
B05B 12/04

(52) UK CL (Edition K)
B2F FJE FJF FJG F120
B8U UAC UGB
U1S S1050

(56) Documents cited
None

(58) Field of search
UK CL (Edition K) B2F FJE FJF FJG
INT CL[5] B05B 12/04
Online databases: WPI

(71) Applicant
DMW (Technology) Limited

(Incorporated in the United Kingdom)

14 Wilford Bridge Spur, Melton, Woodbridge, Suffolk, IP12 1RJ, United Kingdom

(72) Inventor
Stephen Terence Dunne

(74) Agent and/or Address for Service
D Young & Co
10 Staple Inn, London, WC1V 7RD, United Kingdom

(54) Dispensing device

(57) A device for delivering a fluid as a spray of droplets, comprises:
a. means for storing a plurality of individual doses of a fluid;
b. pressurising means for applying a pulse of pressure to the storage means to eject an individual dose of the fluid from the storage means; and
c. means for providing an atomising aperture associated with each individual dose for forming the fluid into a spray of droplets.

The invention also provides a presentation of the medicament suitable for use in the device of the invention.

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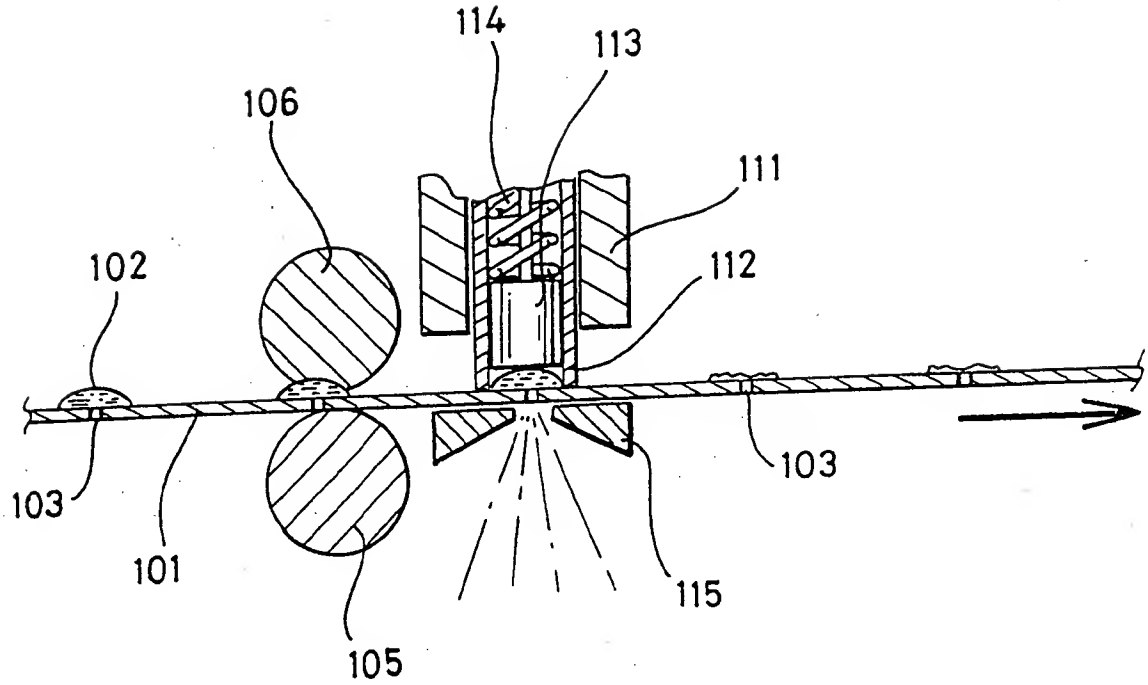

Fig. 1

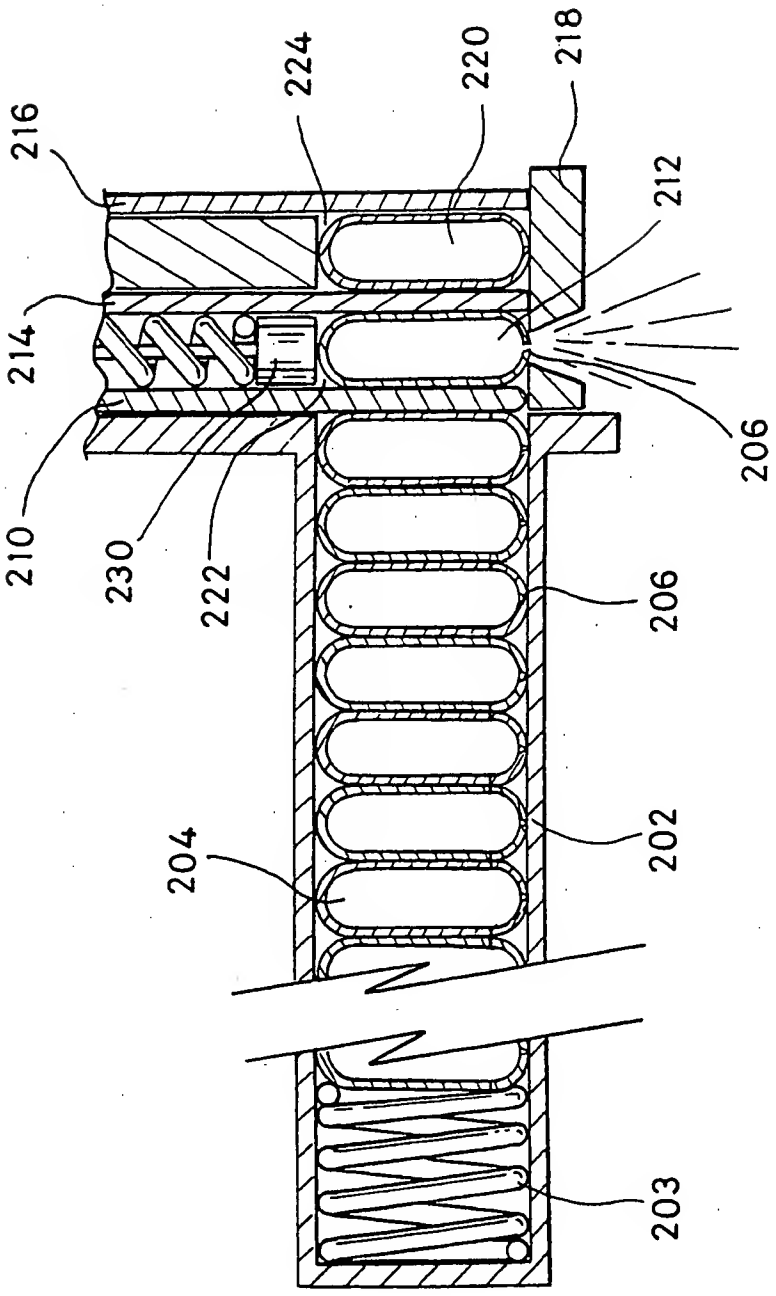

Fig. 2

TITLE: DISPENSING DEVICE

The present invention relates to a dispensing device, notably to an atomising devices and methods for dispensing fluids using them, particularly to self-contained hand-held devices for dispensing a fluid medicament as droplets of a mean size less than about 10 to 12 micrometres without the use of pressurised gas or liquefied propellants, and to methods for administering fluid droplets to a locus, notably medicaments to the nasal passages or lungs.

BACKGROUND TO THE INVENTION:

Fluid drugs can be applied by a number of methods, for example by the atomization of the fluid through a nozzle to form a fine spray of the medicament which can be inhaled by the user. Atomization of the fluid is assisted by creating significant secondary flows or eddies in the fluid entering the nozzle orifice, for example by using a swirl chamber; or by impaction of the fluid as it issues from the nozzle orifice onto a solid static or vibrating surface; or by impacting two liquid jets into one another.

The fluid is ejected through the atomising means by high pressure. This can be generated by a pressurised propellant gas which acts on the fluid medicament contained within the some container as the propellant gas. However, mechanical dispensing means have been proposed, for example a piston in cylinder type of pump, notably one which is biassed by means of a spring so as to generate high operating pressures. With such mechanical devices, the fluid to be dispensed is drawn from a reservoir and discharged under pressure through the atomising nozzle. Typically, two flow control means, for example non-return valves, are provided, one on the exit side of the mechanical dispenser to prevent air ingress

through the nozzle on the suction stroke of the pump or other pressuring device, and the other on the inlet side to the pump to prevent back flow of liquid into the reservoir when the pump is operated on its pressure stroke.

Preferably, the fluid, for example an aqueous solution of a medicament, is held within a replaceable reservoir so that the device can be used repeatedly and the supply of medicament or other fluid replaced from time to time. The reservoir is sealed from the atmosphere to prevent contamination from the environment and requires the use of a sterilant or preservative where the fluid is likely to remain in the reservoir for a prolonged period. This introduces a secondary component into the medicament composition, which may be undesirable.

Typically, the fluid is dispensed through very fine nozzle orifices, eg less than 10 micrometres, to form an atomised spray. It is therefore necessary to provide a filter in the fluid line from the reservoir to the nozzle orifice to minimise blockage of the nozzle. This carries a cost penalty.

We have now devised an alternative form of reservoir for the fluid which reduces the above problems and which permits the use of a different atomizing nozzle for every dose of the fluid which is to be dispensed. This reduces the risk of nozzle blockage, and hence the need for filtration of the fluid. In the design of the invention, individual doses of the medicament are stored in their own reservoirs incorporating their own atomising means. This also eliminates the need for non-return valves or the like further simplifying the design of the fluid dispensing device; and the risk of contamination of the medicament from

the atmosphere or from residual medicament from a previous operation of the dispensing device.

SUMMARY OF THE INVENTION:

According to the first aspect of the present invention, there is provided a device for delivering a fluid, preferably a metered quantity of fluid, as an atomised spray, preferably a spray of an aqueous solution of a medicament, which device comprises:

a. means for storing a plurality of individual doses of a fluid, preferably of metered quantities of fluid;

b. pressurising means for applying a pulse of pressure to the storage means to eject an individual dose of the fluid from the storage means; and

c. means for providing an atomising aperture associated with each individual dose for forming the fluid into a spray of droplets.

Preferably, the storage means comprises a series of individual metered doses of fluid each within a container which is adapted to be presented sequentially to the pressurising means. The container is preferably formed so that it is collapsible when pressure is applied to it. Thus, each container is for example a rupturable plastic or other capsule or other container, for example a blister or bubble formed in a plastic sheet to provide the container for the fluid, bonded to a second sheet of plastic, metal foil or other closure to the blister or bubble. Typically, such a construction is formed as a ribbon or bandolier of individual blisters on a carrier strip or the like which can be passed sequentially through a dispensing device. Alternatively, the containers can be provided as a plurality of discrete self-contained or unitary units which are presented individually to the pressurising means.

The container can be formed so that it can be ruptured when the pulse of pressure is applied to it. Thus, the container wall can be formed with a point or line of weakness therein which ruptures when the pressure is applied. Where the dispensing device is provided with an atomizing means, the fluid released from the container can be atomized by passage through that atomising means. However, it is preferred that the container incorporate its own individual atomizing means in operative association or relationship with the contents of the container through which the contents of the container are discharged. Thus, the container wall can incorporate a small nozzle orifice of the correct shape and size to achieve atomization of the liquid to the correct particle size, for example the orifice preferably has an hydraulic diameter under 100 micrometres, for example 1 to 50, and preferably 1 to 20 micrometres for a drug to be delivered to the lungs. The orifice can be generally circular in plan shape, but can be of irregular shape, for example with a minimu to maximum radial dimension ratio of more than 2:1, for example as much as 5:1 or 10:1 or more. The orifice can be temporarily sealed for transport and storage before use by a rupturable film applied over the orifice or a plug of wax or thermoplastic polymer applied into and/or over the orifice which is expelled when the containers is pressurised. Alternatively, the orifice can be provided by a spot weakness in the wall of the container which ruptures when the pressure is applied to form a nozzle aperture.

In a particularly preferred form, the container for the fluid is a cartridge, capsule or sachet containing a single measured dose of the fluid, with an atomising nozzle or orifice formed in one wall thereof, for example at one end. In this way, each dose of medicament is held in an individual container prior to use and is dispensed through a one time use orifice.

The pressurising means is one which imparts a pulse of pressure to the storage means so as to eject the contents thereof through the atomising means. Thus, the storage means can be collapsed rapidly by a pulse of pressurised gas applied to the walls thereof. However, it is preferred to apply the pulse of pressure by means of a mechanical device acing directly on a wall of the storage means so as to collapse the storage means and eject the fluid therefrom through the atomising means. The mechanical means is, for example, a spring loaded plunger which strikes the storage means against an anvil or other support means. Thus, for example, the dispensing device can contain a spring loaded plunger travelling in a suitable guide mechanism having the storage means transported transversely of the line of travel of the plunger so that, as the plunger travels under the bias of the spring, it strikes the storage means to eject the contents thereof. Preferably, the spring is provided with a detent or latch whereby it can be retained in the loaded position with the storage member under ambient pressure until the plunger strikes it.

DESCRIPTION OF DRAWINGS:

To aid understanding of the invention a preferred form thereof will now be described by way of illustration with reference to the accompanying diagrammatic drawings, in which Figure 1 is a sectional view of one embodiment of the invention where the fluid is stored in blister packs; and Figure 2 is a sectional view of another embodiment of the invention where the fluid is stored in sachets or cartridges which are held in a magazine and fed individually when required.

DESCRIPTION OF THE PREFERRED EMBODIMENTS:

As shown in Figure 1, a carrier strip or tape 101 of a metal foil or semi-rigid plastic has a series of blisters 102 attached to it to form a series of individual dose containers. The blisters contain the fluid to be dispensed. In order to maximise the effect of the impact of the plunger of the dispensing device as described below, the blisters are preferably substantially filled with the fluid to be dispensed. Such strings of fluid filled blisters can be made using conventional fluid dose manufacturing techniques.

Preferably, each blister is provided with its own atomising means 103 through which the contents of the blister are ejected when the blister is collapsed as described below. Preferably, the atomizing means comprises a nozzle orifice which is formed integrally with the tape 101 in register with each blister 102. For example, the atomizing nozzle comprises a small aperture pre-formed in the metal foil of the tape 101 and temporarily sealed closed by applying a thin plastic film over the tape.

The dispensing device comprises a means for transporting the blisters sequentially into register with a means for applying a sharp pulse of pressure to the blister so as to rupture or collapse the blister and eject the fluid through the atomising means. Thus, the tape 101 is movable by the nip of two opposed rollers 105, 106 so as to locate a blister 102 under a pressure generator 111. Alternatively, other tape transport means can be used, for example a pawl and ratchet drive engaging drive holes in the edge of the tape.

The pressure generator 111 comprises, for example, a movable clamp 112 which is used to hold the tape or the blister 102

in position against a support block or plate 115. A pressurising piston or plunger 113 (shown in the loaded position) acts transversely of the line of travel of the tape 101 to impact upon the blister 102 and collapse it against the support 115. Preferably, the plunger 113 is powered by a spring 114 which is cocked by any suitable cocking mechanism (not shown) to engage a detent which retains the spring in the compressed state until released by a trigger mechanism (not shown). Preferably, the cocking mechanism is interlinked with the other operative parts of the device so that it lifts both the clamp 112 and the plunger 113 and rotates the rollers 105, 106 so as to position a blister 102 in the line of travel of the plunger 113 and to release the clamp 112 to secure the blister 102 in this position.

When the trigger mechanism is actuated, the plunger 113 is released and descends under the drive of the spring to strike the top face of the blister 102 and thus generate a high pressure, typically as much as 3-400 bars, within the blister. The liquid is forced through the atomising orifice 103 in tape 101 and atomises to give a spray of the fluid.

As indicated above, the atomising orifice 103 can be covered with a thin layer of film or wax to prevent the ingress of foreign matter into and escape of fluid from the blister 102. Such temporary closures of the apertures are formed so that they are readily blown away when the fluid is pressurised. Alternatively, the temporary closure can be stripped off the tape by the user or by part of the feed mechanism immediately prior to use.

Such a dispensing system provides the advantages that the atomising orifices only need to function once and hence blockage from suspended particles will be less common. Also

ingress of foreign matter and hence contamination is reduced since the fluid is completely sealed from the outside until used.

In the alternative form of device shown in Figure 2, a magazine 202 holds a number of separate cartridges 204, for example gelatin, plastic, metal foil or other capsules, which are full of the fluid to be atomised. The cartridges 204 have an atomising nozzle 206 formed as an integral part thereof. The magazine 202 has a biassing means 203, for example a spring, which keeps the cartridges 204 bunched close together and biased towards an outlet from the magazine for feeding the cartridges individually to the space below a spring loaded plunger 230 which acts transversely to the line of advance of the cartridges. A plate 210 moves in and out of register with the outlet, for example by a sliding motion, to separate the cartridges within the magazine from the one 212 ready to be used.

The space below the plunger 230 is defined by two further plates 214 and 216 which are also slidably mounted to allow a cartridge 212 to enter the space below the plunger from the magazine 202 and to allow a used cartridge 220 to discharge from the space below the plunger, optionally via a second chamber formed between walls 216 and 214. A transverse support plate 218 forms the base to the space below the plunger and forms the anvil against which the plunger acts to collapse the cartridge 212. Plate 218 is provided with an aperture which registers with the atomising nozzle 206 of the cartridge 212 when this is located in the space below the plunger.

To operate this form of the dispensing device, the slidable plate 214 is first raised to allow a spent cartridge 220 to be ejected or merely to fall away under gravity from the

space below the plunger. The plate 214 then returns to the position shown in Figure 2 to form a side wall to the space beneath the plunger. In order to retain the spent cartridge in the device for tidy disposal at a later time, the second plate 216 can be provided to form a second chamber 224 into which the spent cartridge 220 from the space below the plunger is discharged and retained. The slidable plate 210 is then raised, allowing a new cartridge to enter the space below the plunger from magazine 202. When plate 210 returns to its lowered position, the plates 210 and 214 form, with plate 218, a firing chamber 222 within which the cartridge 212 is located. A cocking mechanism (not shown) is provided to lift all three sliding plates and the piston in turn to load and discharge cartridges from the firing chamber 222.

When a cartridge 212 is located in firing chamber 222, a spring loaded piston 230 is allowed to impact upon the cartridge to pressurise the contents of the cartridge, ejecting the contents through the atomising means 206. The pressure generated is typically 3-400 bars. As with the earlier form of device, the atomising orifice 206 can be covered with a thin layer of plastic film or a wax, which ruptures at use or is removed prior to use, to prevent the ingress of foreign matter into the stored drug.

In an alternative arrangement, individual cartridges are inserted into the firing chamber one at a time, eliminating the need for a magazine holder.

The invention has been described above in terms of a blister or cartridge where an atomising nozzle is provided and this then temporarily sealed with a removable or rupturable seal. However, it is within the scope of the present invention to provide the nozzle orifice by rupturing a weakened or thinned area of the tape or cartridge wall. Alternatively,

the end face of the plunger 113 or 230 can carry an axial fine pin or blade which pierces the blister and tape or both end walls of the cartridge to form apertures through which the contents are discharged.

The invention has been described above in terms of generating the pulse of pressure with a spring driven plunger. However, the pressure could be applied by passing the tape or cartridge through a pair of rollers so that the nip of the rollers collapses the blister or cartridge. Likewise the tape for holding the blisters could be manufactured from stainless steel, plastic or other strong material while the blisters could be manufactured from thin metal foil or plastic film. The atomising hole could be produced by laser drilling or chemical machining the wall of the tape or cartridge instead of providing an atomizing nozzle member.

Atomization of the fluid can be assisted by impacting the stream of fluid from the nozzle orifice onto a solid impinger, or a double liquid jet of fluid could be formed by the use of two nozzle orifices and these impinged upon one another. In the case of the solid impinger this could be formed as part of the main body of the device and hence re-used on every shot; as part of the blister tape as a wire in front of the atomising hole and used once per shot; or as a separate component.

We believe that the presentation of individual doses of a fluid, notably an aqueous solution of a medicament, in a container, for example a cartridge or blister, having a collapsible configuration and provided with an atomising nozzle orifice, which is preferably temporarily sealed, are novel, and the invention therefore also provides such a presentation comprising a predetermined quantity of a

medicament in a container, the container being collapsible upon the application of pressure thereto so as to discharge the contents of the container, the container being provided with an atomising nozzle or aperture in a wall thereof through which the contents of the container can be discharged upon pressurisation of the container.

CLAIMS:

1. A device for delivering a fluid as a spray of droplets, which device comprises:

a. means for storing a plurality of individual doses of a fluid;

b. pressurising means for applying a pulse of pressure to the storage means to eject an individual dose of the fluid from the storage means; and

c. means for providing an atomising aperture associated with each individual dose for forming the fluid into a spray of droplets.

2. A device as claimed in claim 1, wherein the storage means comprises a series of individual metered doses of fluid each within a container which is adapted to be presented to the pressurising means.

3. A device as claimed in either of claims 1 or 2, wherein the storage means is provided with an atomising nozzle or aperture in a wall thereof in operative association with each individual dose of the fluid through which the individual doses of fluid are adapted to be discharged upon pressurisation of the storage means.

4. A device as claimed in any one of the preceding claims, wherein the wall of the storage means is provided with an area of weakness in operative association with each individual dose of the fluid, whereby the atomising aperture is formed in situ at this area when the storage means is pressurised.

5. A device as claimed in any one of the preceding claims, wherein the pressurising means is a spring loaded plunger adapted to impact upon the storage means.

6. A device as claimed in claim 5, wherein there is provided a means for transporting the storage means transversely of the line of travel of the plunger so as to bring the individual doses in the storage means into register with the line of travel of the plunger.

7. A device as claimed in any one of the preceding claims, wherein the storage means is in the form of a plurality of discrete unitary units and a magazine is provided to contain such units and to feed them sequentially to the pressurising means.

8. A device as claimed in claim 7, wherein the magazine comprises a spring loaded mechanism for feeding the units via a gate mechanism to a chamber upon which the pressurising means acts, the chamber having an outlet aperture adapted to register with the atomising aperture of the unit through which the contents of the unit can discharge upon pressurisation of the unit.

9. A device as claimed in any one of claims 1 to 6, wherein the storage means is in the form of individual containers carried by a carrier strip and the device is provided with means for advancing the carrier strip to bring the containers into register with the pressurising means.

10. A device as claimed in claim 9, wherein the advance means comprises a pair of rollers and the carrier strip is adapted to pass through the nip between the rollers.

11. A device as claimed in claim 1, wherein the pressurising means carries a means for piercing the storage means whereby an atomising aperture in the wall of the storage means in operative association with an individual dose of the fluid can be formed in situ.

12. A device as claimed in claim 1 substantially as hereinbefore described.

13. A device as claimed in claim 1, substantially as hereinbefore described with respect to and as shown in either of Figures 1 or 2 of the accompanying drawings.

14. A device as claimed in any one of the preceding claims, wherein the storage means containing a fluid medicament.

15. A device as claimed in claim 14, wherein the medicament is an aqueous solution of a medicament.

16. A storage means adapted for use in a device as claimed in any one of the preceding claims, which storage means comprises a predetermined quantity of a medicament in a container, the container being collapsible upon the application of pressure thereto so as to discharge the contents of the container, the container being provided with an atomising nozzle or aperture in a wall thereof through which the contents of the container can be discharged upon pressurisation of the container.

17. A storage means as claimed in claim 16, wherein the container is in the form of a discrete unitary unit and the unit is provided with an atomising nozzle or aperture in a wall thereof.

18. A storage means as claimed in claim 16, wherein the container is provided upon a carrier strip.

19. A storage means as claimed in claim 16 substantially as hereinbefore described.

20. A storage means as claimed in claim 16 substantially as hereinbefore described with respect to and as shown in either of Figures 1 or 2 of the accompanying drawings.

Examiner's report to the Comptroller under Section 17 (The Search Report)

Application number 9208178.5

Relevant Technical fields

(i) UK Cl (Edition K) B2F (FJE, FJF, FJG)

(ii) Int CL (Edition 5) B05B 12/04

Search Examiner

S I AHMAD

Databases (see over)

(i) UK Patent Office

(ii) ONLINE DATABASE: WPI

Date of Search

29 JULY 1992

Documents considered relevant following a search in respect of claims 1 TO 20

Category (see over)	Identity of document and relevant passages	Relevant to claim(s)
	NONE	

Category	Identity of document and relevant passages	Relevant to claim(s)

Categories of documents

X: Document indicating lack of novelty or of inventive step.

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